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10/716,346	11/18/2003	Ming Zheng	CL2221USNA	7632

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,346

Applicant(s)

ZHENG ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 23 March 2006 in which claims 21 and 25 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 6 December 2005 under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 103(a), not reiterated below, are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 21-27 are under prosecution.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1634

The recitation “the carbon nanotube lacks a member of a binding pair” is recited in Claim 25 from which Claim 26 depends. Applicant points to Example 1-7 wherein neither the nucleic acid or nanotube possess a binding pair member. Applicant further points to the passage beginning on page 11 wherein the discussion of binding pair incorporation is limited to nucleic acids. The passages are noted but are not convincing. The passages describe incorporation of binding pair members into nucleic acids and describe use of unfunctionalized nanotube. However, the cited passages nor the specification as a whole describe the nanotubes as lacking a member of a binding pair as claimed. Furthermore, the specification specifically teaches nanotube having a member of a binding pair e.g. nucleic acids (page 4, lines 32-38 and page 5, lines 21-23).

While the specification teaches unfunctionalized nanotubes (page 3, line 16 and as recited in Claim 21). However, the specification does not define the nanotube as further limited to lacking a member of a binding pair.

The recitation of lacking a member of a binding pair is a negative limitation that does not have basis in the originally filed disclosure. And the courts have stated that the mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph. (MPEP § 2173.05(i).

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not

Art Unit: 1634

described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

35 U.S.C. 112: second paragraph

reiterated from previous action

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 26 are indefinite in Claim 25 for the recitation “provided however that the CNT lacks a member of a binding pair.” The recitation is indefinite for the language “provided however” because it is unclear whether the following recitation is an optional or required limitation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1634

7. Claims 21-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al (Advanced Materials, 1998, 10(9): 701-703) in view of O'Connell et al (Chemical Physics Letters, 2001, 342: 265-271).

Regarding Claim 21, Guo et al discloses a complex comprising a carbon nanotube bound to a nucleic acid molecule by non-covalent means (page 701, last paragraph). Guo et al are silent regarding the nanotube structure being single walled or multiwalled.

However, dispersed and unfunctionalized single-walled nanotubes (SWNT) were well known in the art at the time the claimed invention was made as taught by O'Connell et al. O'Connell et al teach a similar complex comprising SWNT and a non-covalently associated linear polymer (Abstract). O'Connell et al further teach that SWNT have "remarkable mechanical and electrical properties" and the dispersion of the SWNT allows the complexes to be reliably manipulated in solution phase techniques e.g. as chemical reagents (page 265, paragraphs 1-2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the dispersion of SWNT of O'Connell et al to the nanotube complex of Guo et al for the expected benefit of reliable manipulation of nanotube-nucleic acid complexes in solution phase assays as desired in the art (O'Connell, page 265).

Regarding Claim 22, Guo et al disclose the complex wherein the nucleic acid is DNA (page 701, last paragraph, lines 6-10).

Regarding Claim 23, Guo et al disclose the complex wherein the nucleic acid is substantially isolated from nature (page 701, last paragraph, lines 6-10).

Regarding Claim 24, Guo et al disclose the complex wherein the nucleic acid is between 10 and 1000 bases (page 701, last paragraph, lines 6-10).

Regarding Claim 27, Guo et al disclose the complex wherein the nucleic acid is metallized i.e. platinated (page 701, last paragraph, lines 6-10).

Response to Arguments

8. Applicant asserts that Guo et al teach double stranded nucleic acids while the instant invention is drawn to single stranded nucleic acids. The argument has been considered but is not found persuasive because the instant claims are drawn to “nucleic acid molecule” and are not limited to single stranded nucleic acids as asserted. Furthermore, the instant specification defines nucleic acid molecules as either single- or double-stranded (page 4, lines 32-35).

Therefore, the argument is not commensurate in scope with the claims.

Applicant further asserts that the binding properties of linear polymers taught by O’Connell are “vastly different than those of single stranded DNA” and therefore one of ordinary skill would have no reason to assume that the polymer association of the linear polymers with the CNT would teach anything about the association of single stranded nucleic acid with CNT. The argument has been considered but is not found persuasive. First, as stated above, the claims are not limited to single stranded nucleic acids. And second, applicant assertion of “vastly different” properties is not supported by any factual evidence of such difference. As such, the assertion is deemed to be unsupported arguments of counsel.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (see (MPEP 716.01(c)).

9. Claims 21-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsang et al (Angew, Chem. Int. 1997, 36 (20): 2198-2200) in view of O’Connell et al (Chemical Physics Letters, 2001, 342: 265-271).

Regarding Claim 21, Tsang et al discloses a complex comprising a carbon nanotube bound to a nucleic acid molecule by non-covalent means i.e. adsorbed DNA (page 2199 and Fig. 3). Tsang et al are silent regarding the nanotube structure being single walled.

However, single-walled nanotubes (SWNT) were well known and preferred in the art at the time the claimed invention was made as taught by O'Connell et al. O'Connell et al teach a similar complex comprising SWNT and a non-covalently associated linear polymer (Abstract). O'Connell et al further teach that SWNT have "remarkable mechanical and electrical properties" and the dispersion of the SWNT allows the complexes to be reliably manipulated in solution phase techniques e.g. as chemical reagents (page 265, paragraphs 1-2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the dispersion of SWNT of O'Connell et al to the nanotube complex of Tsang et al for the expected benefit of reliable manipulation of nanotube-nucleic acid complexes in solution phase assays as desired in the art (O'Connell, page 265).

Regarding Claim 22, Tsang et al disclose the complex wherein the nucleic acid is DNA (page 2198, right column).

Regarding Claim 23, Tsang et al disclose the complex wherein the nucleic acid is substantially isolated from nature (page 2198, right column).

Regarding Claim 24, Tsang et al disclose the complex wherein the nucleic acid is between 10 and 1000 bases (page 2198, right column, line 2).

Regarding Claim 25, Tsang et al disclose the complex wherein the nucleic acid is functionalized with a member of a binding pair i.e. the DNA comprises a sequence having a complementary binding partner and the nanotube lacks the complementary sequence (page 2198, right column).

Regarding Claim 27, Tsang et al disclose the complex wherein the nucleic acid is metallized i.e. platinated (page 2198, right column).

Response to Arguments

10. Applicant reiterates the arguments discussed above regarding Gao in view of O'Connell. The arguments have been considered but are not found persuasive because the claims are not limited to single stranded nucleic acids.

11. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massey et al (U.S. Patent No. 5,866,434, issued 2 February 1999) in view of O'Connell et al (Chemical Physics Letters, 2001, 342: 265-271).

Regarding Claim 21, Massey et al discloses a dispersed (Example 6, Column 45) complex comprising a carbon nanotube bound to a nucleic acid molecule by non-covalent means i.e. biotinylated DNA is bound avidin adsorbed onto the nanotube (Column 40, lines 41-50). Massey et al are silent regarding the nanotube structure being single walled.

However, single-walled and unfunctionalized nanotubes (SWNT) were well known and preferred in the art at the time the claimed invention was made as taught by O'Connell et al. O'Connell et al teach a similar complex comprising SWNT and a non-covalently associated linear polymer (Abstract). O'Connell et al further teach that SWNT have "remarkable mechanical and electrical properties" and the dispersion of the SWNT allows the complexes to be reliably manipulated in solution phase techniques e.g. as chemical reagents (page 265, paragraphs 1-2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the dispersion of SWNT of O'Connell et al to the nanotube complex of Massey et al for the expected benefit of reliable manipulation of nanotube-nucleic acid complexes in solution phase assays as desired in the art (O'Connell, page 265).

Art Unit: 1634

Regarding Claim 22, Massey et al disclose the complex wherein the nucleic acid is DNA (Column 40, line 47).

Regarding Claim 23, Massey et al disclose the complex wherein the nucleic acid is substantially isolated from nature (Column 40, lines 41-50).

Regarding Claim 24, Massey et al disclose the complex wherein the nucleic acid is between 10 and 1000 bases (Example 6, Column 45, lines 18-20 and Fig. 4).

Regarding Claim 25, Massey et al disclose the complex wherein the nucleic acid is functionalized with a member of a binding pair i.e. tag wherein the nanotube lacks a tag-binding pair (Example 6, Column 45, lines 18-20 and Fig. 4).

Regarding Claim 26, Massey et al disclose the complex wherein the binding pairs are streptavidin/biotin (Column 40, lines 45-46; Example 6, Column 45, lines 18-20; and Fig. 4).

Regarding Claim 27, Massey et al disclose the complex wherein the nucleic acid is metallized i.e. via hybridization with $\text{Ru}(\text{bpy})_3^{2+}$ tag (Column 40, lines 47-50; Example 6, Column 45, lines 18-20; and Fig. 4).

Response to Arguments

12. Applicant reiterates the arguments discussed above regarding Gao in view of O'Connell. The arguments have been considered but are not found persuasive because the claims are not limited to single stranded nucleic acids.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1634

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 21-23 and 25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 19 of copending Application No. 10/716,347. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to carbon nanotube-nucleic acid complexes and differ only in the '347 complexes are defined by the process of making. However, both claim sets define the same product as defined by their structures. Therefore, the products are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant

15. Applicant states that the '347 claims are drawn to a population of complexes while the instant claims are drawn to single complex. Applicant re-asserts that the '347 complexes are patentably distinct from those instantly claimed because the '347 claims are written in product-by-process form. The argument has been considered but is not found persuasive because the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

The rejection is maintained.

Art Unit: 1634

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

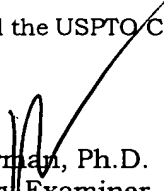
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1634

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
May 31, 2006